DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M–0172, 2004M–0309, 2004M–0433, 2004M–0341, 2004M–0356, 2004M–0403, 2004M–0310, 2004M–0312, 2004M–0313, 2004M–0342, 2004M–0323, 2004M–0345, 2004M–0350, 2004M–0387, 2004M–0415, 2004M–0388, and 2004M–0430]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

ch0467

NAD1

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from

July 1, 2004, through September 30, 2004. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2004, THROUGH SEPTEMBER 30, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020026/2003M–0172	Cordis Corp.	CYPHER SIROLIMUS-ELUTING CORONARY STENT ON THE RAPTOR OVER-THE-WIRE DELIVERY SYSTEM OR RAPTORRAIL RAPID EXCHANGE DELIVERY SYSTEM	April 24, 2003
P020023/2004M–0309	Q-Med Scandinavia, Inc.	RESTYLANE INJECTABLE GEL	December 12, 2003
P030044/2004M–0433	DakoCytomation California, Inc.	DAKOCYTOMATION EGFR PHARMDX	February 12, 2004
P030024/2004M–0341	Ortho-Clinical Diagnostics, Inc.	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC REAGENT PACK AND CALIBRATOR	March 4, 2004
P030026/2004M–0356	Ortho-Clinical Diagnostics, Inc.	VITROS IMMUNODIAGOSTIC PRODUCTS ANTI-HBC IGM REAGENT PACK AND CALIBRATOR	March 4, 2004
P030025/2004M–0403	Boston Scientific Corp.	TAXUS EXPRESS2 PACLITAXEL-ELUTING CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	March 4, 2004
P020030/2004M–0310	Ela Medical, Inc.	STELID II/STELIX/STELIX II ENDOCARDIAL PACING LEAD	June 17, 2004
P970043 (S015)/2004M–0312	Alcon Laboratories, Inc.	LADARVISION 4000 EXCIMER LASER SYSTEM	June 29, 2004
P030054/2004M–0313	St. Jude Medical, Inc.	ST. JUDE MEDICAL EPIC HF SYSTEM	June 30, 2004
P040008/2004M–0342	bioMerieux, Inc.	VIDAS TPSA ASSAY	July 8, 2004
P030012/2004M–0323	R2 Technology, Inc.	IMAGECHECKER CT CAD SOFTWARE SYSTEM (MODEL LN–1000)	July 8, 2004
P010061/2004M–0345	Photo Cure, ASA	CURELIGHT BROADBAND (MODEL CURELIGHT 01)	July 28, 2004
P030050/2004M–0350	Dermik Laboratories	SCULPTRA	August 3, 2004
P030010/2004M–0387	Siemens Medical Solutions USA, Inc.	SIEMENS MAMMOMAT NOVATIONDR FULL FIELD DIGITAL MAMMOGRAPHY SYSTEM	August 20, 2004
H030009/2004M–0415	Synthes (USA)	VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)	August 24, 2004
P040012/2004M–0388	Guidant Corp.	ACULINK CAROTID STENT SYSTEM & RX ACCULINK CAROTID STENT SYSTEM	August 30, 2004
P010012 (S026)/2004M–0430	Guidant Corp.	CONTAK CD (MODEL 1823), CONTAK CD 2 (MODELS H115 & H119), RENEWAL (MODEL H135), RENEWAL 3 (MODELS H170, H175, H177, & H179)	September 14, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: 12/3/04
December 3, 2004.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S